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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Subject: **Docket No. 00D-1539**
Draft Guidance for Industry, Electronic Records; Electronic Signatures, Maintenance of Electronic Records

26 November, 2002

Dear Sir/Madam:

Thank you for the opportunity to comment on the Draft Guidance for Industry, Electronic Records; Electronic Signatures, Maintenance of Electronic Records published in the Federal Register on September 5, 2002. Below are Genzyme's comments for your consideration.

1. §5.1 Bullet Point 1 establishes a "maintenance" requirement, but fails to define FDA's expectations as to appropriate maintenance.
2. In §5.1 Bullet Point 3, please state whether "(r)etrieval and access restrictions" refer to physical, logical, or both types of restrictions.
3. The phrase "(d)ata encoded within an electronic record . . . " in §5.2 Bullet Point 1 is unclear. Please provide a more descriptive example.
4. Please add the term "flash memory" found in §5.2 Bullet Point 3 to the glossary.
5. What is intended by the recommendation in §5.3 to " . . . periodically access a representative number of electronic records . . . ?" Is the recommendation to access a representative number of records for each type of storage medium, a representative number of units of each storage media, or a representative number of records on each unit of storage media?
6. The last paragraph in §5.3 seems inconsistent with the previous statements found in this section. Please clarify whether "back up" refers to retention records or routine system back up and restore processes.
7. Please clarify the expectation for "monitoring," and state if the Agency is imposing validation requirements through §5.4.
8. Please define "process" on §5.5, and specify the record types to which the term applies.
9. We would appreciate illumination as to what records would be subject to the reconstruction mentioned in §5.5. For example, reconstructions of process failures (events) such as an attempt to reload a DCS script that was active during the event would not be desirable, although review of the data gathered as a result of the event failure would be.

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10. In §5.5, please identify the kinds of information expected to have the capacity for reprocessing over the retention timeline.
11. What is intended by the word "format" in §5.5? For example, formats could include database table structure and table properties, file format, or visual human readable e-record with color-coding.
12. §5.6 contains the sentence "(s)ome systems have a built-in copy verification mechanism, such as a cyclic redundancy check . . . ." Is FDA indicating that traditional computer validation does not apply to the redundancy check? Conversely, is validation always required unless the system contains built-in error checking? Please differentiate between the use of the term "validated" as opposed to verification of copied information.
13. As in §5.1, expectations of maintenance are not defined in §6.
14. As upgrades do not necessarily constitute a migration, please define FDA's expectations for migration and conversion as well as upgrade and routine assurance that a system performs as it did when retired in §6.1.
15. The requirement in §6.1 to train personnel on non-used systems is troubling. In addition to utilizing resources, there is the possibility that the training will be inadequate and subject to interpretation by employees with no opportunity to test their own knowledge, even under well documented training programs. For this approach to work, significant resources will need to be devoted toward keeping the system in operable condition to ensure trained personnel are actually trained.
16. Please consider alternatives such as viewers to data burned on static, unalterable media, and emulators that replicate original environments.
17. We also request that FDA consider the use of trusted third parties for verification of data integrity, particularly digital signatures, to guarantee integrity in §6.2.1.
18. Is the term "reconstruct" in §6.2.1.1 intended to mean recreation of a series of events, or is this geared towards predicate rule data captured in controlled environments to be used for forensic purposes? Also, this appears to cover both predicate rule uses for information as opposed to process improvement. Please explain the meaning of the phrase "accurate and complete representation of events . . . actions," and state whether there is an expanded expectation of what audit trails are able to do or should provide.
19. Please note that we consider color to be metadata if used as functional information.
20. In §6.2.1.3, is FDA suggesting that migration requires an audit trail even if the process is validated? Please differentiate between archival, migration, and conversion, and specify front end or back end. Further guidance on handling difficult legacy and/or hybrid electronic/ paper systems over the near term would be most helpful.
21. §6.2.1.3 states that " . . . new links 'ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.'" Please define "ordinary means." If a record that can be migrated and the signatures converted from one technology to another, they can probably be manipulated during the migration.
22. Could a group within a corporation that lacks ownership over the data or application perform the process of data integrity assurance by reapplication of digital signatures by third party?

23. We would be grateful for further guidance regarding the documentation of metadata transformation and unavoidable losses in §6.2.1.5.

Genzyme appreciates the opportunity to comment on the Draft Guidance for Industry, Electronic Records; Electronic Signatures, Maintenance of Electronic Records. Please contact me at (617) 374-7275 or Juliette Shih at (617) 761-8929 should you have any questions regarding this letter.

Cordially,

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